

Cystic Fibrosis advancing care with clinical trials

**UK CF Clinical Trials Accelerator
Platform (CTAP)
Early Phase Infrastructure**



**Fighting for a
Life Unlimited**

Clinical Trials Accelerator Platform

Launched in collaboration with the USA Cystic Fibrosis Foundation (CFF), the Clinical Trials Accelerator Platform (CTAP) is a UK-wide initiative bringing together cystic fibrosis (CF) centres from around the UK to support CF clinical trials.

CTAP provides the infrastructure to support sponsors with delivery of CF clinical trials, and the platform to enable the CF community to gain timely access to these trials. It does this by:


- Bringing together 27 CTAP centres experienced in running CF clinical trials to form the CTAP clinical trials network
- Providing 89% of the UK CF population access to clinical trials – >4,000 babies and children and >5,000 adults
- Funding a national team of 25 trial coordinators to support CF trial set-up and delivery
- Creating a specialist network of CF early phase centres and trial coordinators




CTAP's impact

Since the programme's launch in 2017:


Over 800
people with CF have been screened, and 700 enrolled for a clinical trial



32 CF trials
have been supported by the network of CTAP centres



15 sponsors
have been supported by CTAP with recruitment site identification and feasibility



CTAP support for sponsors

CTAP provides sponsors with the following support for early and late phase clinical trials:

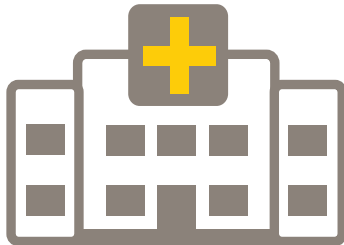
- Support with site identification based on the trial requirements
- National feasibility service based on specified demographics via the UK CF Registry
- Centralised, centre-level feasibility service
- Knowledge of setting up patient identification (referral) centres with established referral pathways
- Facilitated Commercial Involvement (PPI) opportunities with our CF ambassadors, prior to and during study design
- Clinical Trials Digital Hub with CF Trials Tracker database

CTAP early phase infrastructure

A specialist early phase CF network provides the infrastructure, resourcing and expertise to efficiently deliver phase 1 and 2a trials in the UK.

The early phase network includes six CTAP centres:

- Belfast Health and Social Care Trust (Northern Ireland)
- Cardiff and Vale Health Board (Wales)
- Manchester University NHS Foundation Trust (England)
- NHS Lothian (Scotland)
- Royal Brompton and Harefield NHS Trust (England)
- University Hospital Southampton NHS Trust (England)



Each early phase CTAP centre has:

- A dedicated early phase trial coordinator to oversee early phase trial set-up and delivery with access to 24-hour nursing support
- Knowledge of UK regulatory set-up, including for each devolved nation
- Infrastructure to support paediatric and adult early phase CF trials with specialist early phase trial facilities and dedicated clinic spaces
- Formal agreement from the R&D department and National Institute for Health Research (NIHR) Clinical Research Facilities (CRFs) to support early phase CF trials
- Established CF national referral pathways to enable quick referral of patients from around the UK for early phase trial participation

Why choose the UK to open early phase CF trials?

The UK government provides significant financial investment to fund ground-breaking research, as well as the regulatory processes essential for delivery. CF research not only benefits from these investments but is strengthened by additional CF-specific clinical trial networks and funding.

“The UK is a global player in clinical research, and we continue to punch above our weight in early phase trials.”

- The UK Department of Health and Social Care, November 2020

World-renowned regulatory process

- In 2018, the UK ran the third highest number of commercial phase 1 clinical trials in the world, running only fewer trials than the USA and China*
- The Health Research Authority (HRA) is committed to fast-tracking ethics review for phase 1 trials, piloting a new rapid review process in early 2021
- The Medicines & Healthcare products Regulatory Agency (MHRA) is not only a globally respected regulator but one that is supportive of innovative trial designs and ways of working

UK CF community demographics

~10,600 people with CF in the UK,

89% receive their care at a CTAP centre

48.6%
are homozygous F508d;

41.1%
are heterozygous F508d;

10.3%
have a rare mutation**

60.6%
of people with CF in the UK
are 16 years and older**

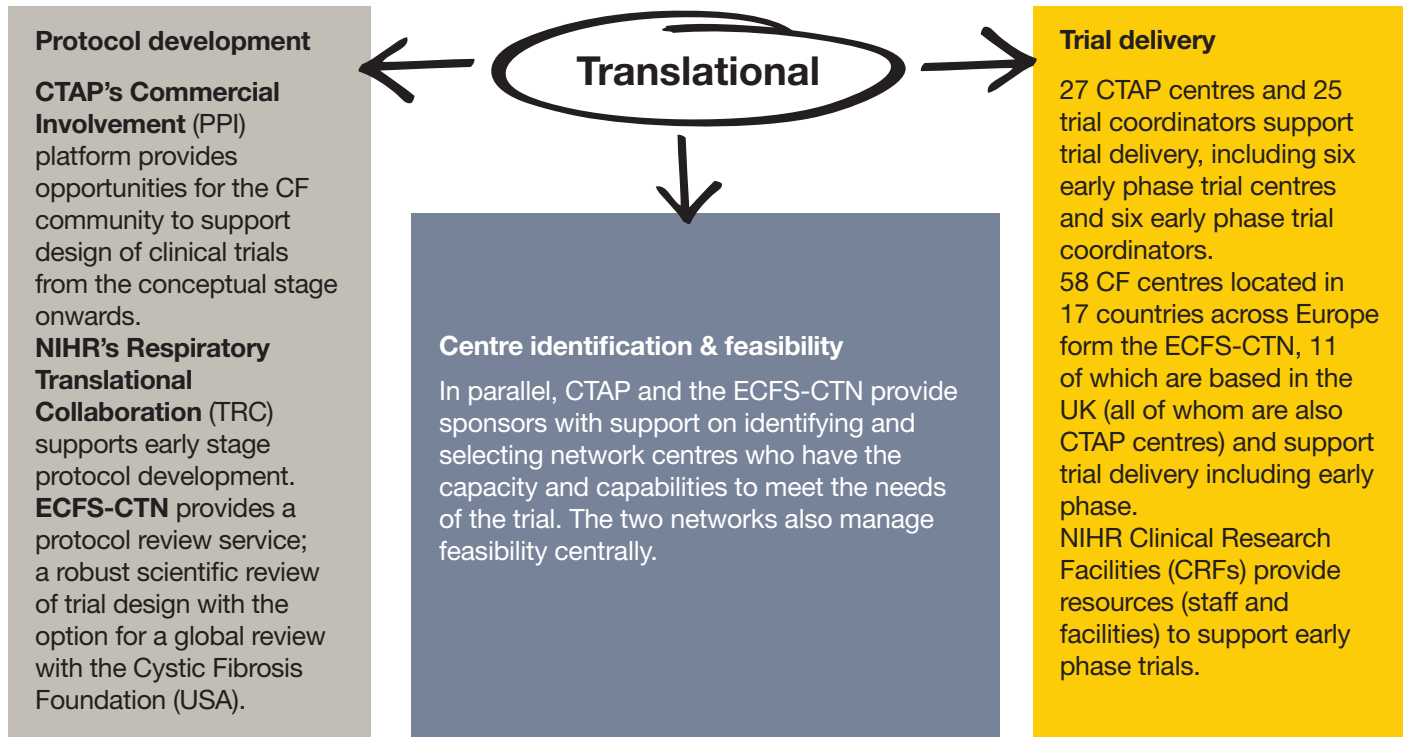
**Data taken from the UK CF Registry 2019 annual report



*Department of Health and Social Care

UK infrastructure to support sponsors with CF translational research delivery

CTAP works closely with the NIHR and ECFS-CTN to ensure sponsors are signposted to the right support at the right time, from the trial design stage onwards. The infrastructure in the UK ensures sponsors are well supported from the trial design stage onwards, helping ensure high quality new CF therapies are developed as efficiently as possible.



UK pathway for support with protocol development, review & adoption



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